

## REMARKS

Claim 118 has been amended to include a semicolon inadvertently left out when the claim was originally presented. Claim 128 has been amended to replace an abbreviation with the full name of the material. No new matter has been added, as it is well known to a person of ordinary skill in the art of anti-plaque/anti-gingivitis agents that "CPC" stands for cetylpyrimidinechloride.

In the outstanding Office Action, a two-way restriction was made. Applicants confirm the election of the claims of Group II (claims 100-136). The Office Action also involves a species restriction. While the Office Action does not clearly identify the different species, it is understood that the species restriction is between chewing gum on the one hand, and apparently other confections, including hard candy, on the other hand. The Office Action states that claims 90 and 118 are generic. While it is unclear just what the other species are, Applicants confirm the election of claims directed to a chewing gum composition. Of the Group II claims, claims 118-120 and 126-136 are generic, and claims 100-117 are directed to the elected species.

Claim 128 was rejected in the outstanding Office Action under 35 U.S.C. § 112, second paragraph, as being indefinite for using the abbreviation "CPC". This abbreviation has been replaced with cetylpyrimidinechloride, the well known anti-plaque/anti-gingivitis agent.

Claims 118 and 131-133 were rejected in the outstanding Office Action under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,626,427 (Wienecke). This rejection is respectfully traversed. Claim 118 is directed to a confectionery product comprising a sweetener; a flavor; and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cardamom oil. Wienecke discloses using cardamom seeds in dragee pearls or chewing bonbons with a sweetener and flavor to make a composition that is used to treat bad breath resulting from consumption of onions, garlic, cigarettes and alcohol. There is no suggestion in Wienecke that cardamom oil can be used in a confectionary product as an antimicrobial agent. Even if it was considered that Wienecke suggested using cardamom oil in a confection, Wienecke would thus not anticipate claim 118.

The term "an effective amount" in the claim introduces a purpose limitation that has to be considered when comparing the claim to the prior art. The United

States patent laws permit a patent to be granted for a new use of either a known composition of matter or a known method. Section 101 of Title 35 provides that a patent may be granted to whoever “invents or discovers any new and useful process.” Section 100 defines the term “process” to include a “new use of a known process . . . [or] composition of matter.” The courts, including the Court of Appeals for the Federal Circuit, have repeatedly held that a patent may be granted for the use of a known composition for a new purpose. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978) and *In re Shetty*, 195 U.S.P.Q. 753 (C.C.P.A. 1977) both unequivocally support this proposition. In both of these cases, the claims were directed to a method of administering a compound to a mammal to accomplish some purpose that was expressed in the claim. In both of these cases, the prior art disclosed methods of administering the same or analogous compounds to mammals, but for a different purpose. In both of these cases, the court reviewed the prior art to determine whether the claimed purpose for using the compound was disclosed, taught or suggested in the prior art. In both of these cases, the court held that the claims were patentable because the prior art failed to disclose, or render obvious, the claimed purpose. Similarly, in the present case, claim 118 calls for an effective amount of an antimicrobial agent comprising cardamom oil. Thus claim 18 calls for the cardamom oil to be present for a purpose not disclosed in the prior art.

The court in *Shetty* determined that claimed purpose for administering the compound, i.e., curbing appetite, was a limitation that must be disclosed or suggested in the prior art. Having found that the claimed purpose was a positive limitation of the claim, the court then set out to determine whether this purpose was disclosed, or rendered obvious, by the prior art. As the Federal Circuit stated in *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990): “In both [the *Marshall* and *Shetty*] cases, the applicant had discovered a completely new use for either an old compound (*Marshall*) or an obvious compound (*Shetty*).” Applicants have likewise discovered a novel and unobvious use (antimicrobial effect when used in confections) for a known compound (cardamom oil). Under the analysis of any of these cases, claim 118 is likewise patentable over Wienecke.

Numerous other decisions have similarly held that a new use of a known process or a new use of a known composition of matter is patentable subject matter. For example, *In re Halleck*, 164 U.S.P.Q. 647 (C.C.P.A. 1970), provides another

example of claims directed to the administration of “an effective amount” of a compound to animals for a specific purpose (stimulating growth) that were found patentable over known, but unrelated, uses of the same compound. Although the court was unsure as to whether the prior art dosages corresponded with the dosages falling within the scope of the claims, the court did find that “the purpose of growth stimulation is not obvious” from the prior art. 164 U.S.P.Q. at 649. The court went on to elaborate that “our view that the ‘exact point’ of novelty lies in the discovery that the agents in question stimulate growth, not in the amount used other than it be an effective amount to stimulate growth.” *Id.* Accordingly, the court found that the purpose recited in the claim was a positive limitation that must be disclosed or suggested in the prior art to render the claim unpatentable.

More recently, the Federal Circuit had the opportunity to address the significance of the “purpose” identified in an “amount effective” type of claim in a pair of cases involving Eli Lilly & Co. In *Eli Lilly & Co. v. A.H. Robins Co.*, 228 U.S.P.Q. 757 (E.D. Va. 1985), the claims at issue were directed to a method of “orally administering to said animal in need of increasing the feed-utilization efficiency an effective propionate-increasing amount of salinomycin.” Although the prior art taught the oral administration of the same compound to chickens for the treatment of coccidiosis, the district court found that the prior art failed to disclose the compound’s use in increasing feed-efficiency. In sustaining the validity of the claim, the court explained that the claims were limited to the purpose for which the compound was being administered: “The Court is satisfied that the language taken in its intended and natural context was to distinguish the claimed use, improvement of feed-efficiency in a ruminant, from [the prior art’s] disclosed use – treatment or prevention of coccidiosis in chickens. It is difficult to envision the claim being more specific. The claim is the measure of the grant.” 228 U.S.P.Q. at 760. The district court’s decision was subsequently affirmed by the Federal Circuit. *Eli Lilly & Co. v. A.H. Robins Co.*, 790 F.2d 95 (Fed. Cir. 1986) (table).

The holding of the Robins decision was specifically addressed by the Federal Circuit in *In re Eli Lilly & Co.*, 14 U.S.P.Q.2d 1741 (Fed. Cir. 1990). This case also involved a claim directed to a method of orally administering a compound for the purpose of increasing the feed-efficiency of ruminant animals. In this case, however, the court found that the prior art disclosed the use of the compound, which was

different than the compound at issue in the Robins decision, to enhance weight gain in animals – a purpose which rendered the claimed purpose obvious. Of significance, however, is the Federal Circuit's distinction of the Robins decision: "In the Robins case, according to the published opinion, the claimed use of salinomycin to enhance weight gain in ruminants was not taught or suggested in the prior art, 228 U.S.P.Q. at 759, unlike the facts of the case at bar." 902 F.2d at 948. The court's analysis is clear; the purpose expressed in "amount effective" claims is a positive limitation that must be disclosed in the prior art to render the claim unpatentable.

Claims directed to the administration of a compound in an "amount effective to accomplish a result" are specialized claims that are common, although not unique, in the pharmaceutical industry. These types of claims have been consistently interpreted as being limited to the claimed purpose for administering the compound. These types of claims were all at issue in the *Marshall, Shetty, Halleck, Robins, and Eli Lilly* decisions discussed above. The correct interpretation of claim 118 is therefore clear – it includes the claimed purpose as a positive limitation. Claims 131-133 are dependent on claim 118, and are thus patentable over Wienecke for the same reasons.

Claims 100-107, 111-120 and 129-136 were rejected in the outstanding Office Action under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,537,595 (Hyodo). This rejection is respectfully traversed. Claim 100 is directed to a chewing gum composition comprising: a gum base; a sweetener; a flavor; and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cardamom oil. As noted above, claim 118 also requires an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cardamom oil. Hyodo discloses a chewing gum composition that can be flavored with, among other flavors, cardamom oil. As with Wienecke, there is no suggestion in Hyodo to use cardamom oil as an antimicrobial agent in chewing gum or other confection. For the reasons explained above, Hyodo thus does not anticipate claim 100 or claim 118, and claims 101-107, 111-117, 119-120, and 129-136 dependent thereon.

Claims 100-103, 105, 111-120, 126, 128-129 and 131-136 were rejected in the outstanding Office Action under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,149,521 (Hirose). This rejection is respectfully traversed. Hirose discloses compositions for use in the oral cavity, including chewing gum. One of several

flavoring agents suggested for inclusion is cardamom oil. However, as with Wienecke, there is no suggestion in Hirose to use cardamom oil as an antimicrobial agent in chewing gum or other confection. For the reasons explained above, Hirose thus does not anticipate claim 100 or claim 118, and claims 101-103, 105, 111-117, 119-120, 126, 128-129 and 131-136 dependent thereon.

Claims 100-103, 111-120, 126, and 128-136 were rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,626,837 (Shimada). This rejection is respectfully traversed. Shimada discloses oral compositions that comprise a cationic bactericide. Because of the cationic bactericide, normal oil soluble flavors are not used in the composition so that anionic and nonionic surfactants can be eliminated. Thus, rather than using cardamom oil, Shimada actually suggest using an aqueous ethanol extraction of the flavor oils, including cardamom oil. Claims 100 and 118 call for cardamom oil, not an alcohol extraction of cardamom oil. Further, there is no suggestion in Shimada that the cardamom oil extract has any antimicrobial use. Thus claims 100 and 118, and claims 101-103, 111-117, 119-120, 126 and 128-136 dependent thereon, are patentable over Shimada.

Claims 108-110 were rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as unpatentable over Hyodo in view of U.S. Patent No. 4,828,845 (Zamudio-Tena). This rejection is respectfully traversed. Hyodo is discussed above. Zamudio-Tena discloses xylitol coated comestibles. There is no suggestion in Zamudio-Tena of using cardamom oil, or that cardamom oil can be used as an antimicrobial agent. Thus, even if Hyodo was combined with Zamudio-Tena, the resulting combination would not suggest a chewing gum composition comprising: a gum base; a sweetener; a flavor; and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cardamom oil, as called for by claim 100. Claims 108-110, dependent on claim 100, are thus patentable over Hyodo and Zamudio-Tena.

Claims 100, 104, 106, 111-118 and 127 were rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,030,605 (D'Ameila) in view of Wienecke. This rejection is respectfully traversed. Wienecke is discussed above. D'Ameila discloses breath freshening compositions, including chewing gum. However, there is no suggestion of using cardamom oil in

D'Ameila. Thus even if D'Ameila was combined with Wienecke, the resulting combination would not suggest a chewing gum composition comprising: a gum base; a sweetener; a flavor; and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cardamom oil, as called for by claim 100, or a confectionery product comprising a sweetener; a flavor; and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cardamom oil as called for by claim 118. Thus claims 100 and 118, and claims 104, 106, 111-117 and 127 are patentable over D'Ameila and Wienecke.

Applicants have made a novel and non-obvious contribution to the art of chewing gum formulations and other confectionery using cardamom oil as an antibacterial agent. The claims at issue distinguish over the earlier cited references and are in condition for allowance. Accordingly, such allowance is now earnestly requested.

Respectfully submitted,

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